**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**

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| **IN RE VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION** | **MDL No. 2875**<br><br>**HON. RENÉE MARIE BUMB** |
| **THIS DOCUMENT RELATES TO:**<br>*Roberts v. Zhejiang Huahai Pharmaceutical Co. Ltd.*,<br><br>Case No. 1:19-md-02875-RMB-SAK | |

# PLAINTIFFS' BRIEF IN SUPPORT OF *DAUBERT* MOTION TO PRECLUDE OPINIONS OF DEFENSE EXPERT ANDREW THOMPSON, PH.D.

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## PRELIMINARY STATEMENT

ZHP's expert in process chemistry, or organic synthesis as he defined it more narrowly, Andrew Thompson, Ph.D., was presented as an expert to provide the following central opinion: "The opinions offered by Drs. Hecht and Najafi regarding what ZHP should have known, prior to 2018, regarding the potential for NDMA formation in valsartan API are unsupported by scientific evidence and are inconsistent with the knowledge, general practice, and concerns held by chemists in the pharmaceutical industry at that time." (Thompson R. 10 (Ex. 1); Thompson Dep. Tr. 168:6-12 (Ex. 2)).[1] However, at his deposition, it was established that he first learned of the existence of nitrosamines after the Valsartan recall in 2018, and it was made clear that he has no reliable basis to offer such an opinion.

Dr. Thompson failed to apply a reliable methodology, basing his opinions on what he knew and would do rather than what ZHP could or should have done. His opinions are untethered to the facts and constitute net opinions. This includes no independent research, baseless speculative interpretations of key documents rather than reliance on sworn testimony in the record, and a lack of understanding of foundational facts. This cannot fairly be termed a coherent methodology.

[1] Unless otherwise noted, all exhibits are from Adam M. Slater's certification in support of this motion.

Dr. Thompson grounds his opinions on what he would have known or done, rather than opining as to what the chemists at ZHP *should* have known and done, since he candidly admits he does not have any basis to opine on what they could or should have done. To illustrate, Dr. Thompson conceded that the scientific literature with regard to the chemicals and substances that caused the formation of the NDMA documented the chemical reactions and accompanying impurities of those chemicals and substances well before the processes were developed and implemented. He sidestepped this important evidence by claiming that he (a process chemist seeking to synthesize small batches of new drug substances for use in pre-commercial clinical trials) would not have known or bothered to search for this literature. But relying on what he would have known or done is not enough.

Dr. Thompson failed to apply any objective or reliable standard. He admitted he did not know or apply the regulatory standards ZHP was expected to apply in investigating the changes to its manufacturing processes—including the requirement to make "every feasible technical effort" to identify and prevent genotoxic impurities. He was not aware that ZHP was required to conduct a scientifically rigorous risk assessment including a search of relevant scientific literature, to identify the risks of use of the chemicals and substances, including formation of impurities. **In fact, he did not perform any literature search whatsoever.** Thus, his opinions are not only based on no reliable methodology, they fail to fit the case.

The Court should bar Dr. Thompson's conclusion-driven opinions in their entirety.

## STATEMENT OF FACTS

Andrew Thompson, Ph.D, is a process chemist as well as founder and former head of J-STAR Research, which is essentially a "department of process research that a company could outsource." (Thompson Dep. Tr. 43:4-6). For example, while at Merck's department of process research between 1987 and 1995, Dr. Thompson worked on an angiotensin two receptor blocker that was never sold commercially. (*Id.* at 18:14-19:5). He "only worked on it up to the laboratory scale," and the risk assessment "was somebody else's responsibility." (*Id.* at 20:2-11). His work at J-STAR was similarly limited. (*Id.* at 31:7-11).

For context, Eric Gu testified that Shanghai Syncores acted as ZHP's department of process research in this case, and Shanghai Syncores' research development report clearly told ZHP: "The synthesis process of crude valsartan and the purification process including the solvent system need to be further optimized at the pilot scale." (Eric Gu 4/5/2021 Dep. Tr. 38:18-22, 138:8-16 (Ex. 3)). In other words, any small-scale process development is just the beginning of the robust, scientifically rigorous process development at issue in this case, but his frame of reference fails to encompass or at least account for what needed to be known at each

step. Dr. Thompson brings minimal applicable experience to this case. (Thompson Dep. Tr. 20:12-15, 33:9-12, 62:15-17, 180:13-18, 181:19-25).

Dr. Thompson admitted that he has never "done any research into nitrosamines," and he first learned of the existence of nitrosamines and NDMA "[a]fter the valsartan recall." (*Id.* at 22:13-15). He "never considered any analytical technique to detect nitrosamines prior to 2018," and in fact never considered "the potential presence of nitrosamines in any drug before 2018 when [he] learned of the valsartan issue." (*Id.* 20:12-21:6, 22:4-15, 24:4-25:1).

Most important, he is not able to apply his knowledge of chemistry in a meaningful way that would fit the case, because he did not perform any search of the literature or apply any objective standards. (*Id.* at 28:19-20, 61:8-62:3, 65:16-22, 85:8-24). He confirmed that his opinions are based solely on his own work. (*Id.* at 53:15-20, 54:3-15). He could not answer "whether ZHP was responsible to identify the potential risk of forming these genotoxic impurities even if it was not, to quote you, obvious and easy to catch." (*Id.* at 67:20-24).

Yet, Dr. Thompson submitted a report purporting to opine as to what ZHP "should have known," in an attempt to defend ZHP's risk assessment for failing to identify the NDMA in its valsartan. (Thompson R. 3-6). His concessions at his deposition should result in preclusion of his opinions.

## THE *DAUBERT* STANDARD

The admissibility of expert testimony is determined pursuant to Federal Rule of Evidence 702. Preliminarily, "Rule 702 requires that the expert's testimony must assist the trier of fact." *In re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717, 742-43 (3d Cir. 1994). The Third Circuit has explained that "admissibility [consequently] depends in part on 'the proffered connection between the scientific research or test result to be presented and particular disputed factual issues in the case.'" *Id.* at 743 (quoting *U.S. v. Downing*, 753 F.2d 1224 (3d Cir. 1985)). Importantly, "scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes." *Id.* "Thus, even if an expert's proposed testimony constitutes scientific knowledge, his or her testimony will be excluded if it is not scientific knowledge **for purposes of the case**." *Id.* (emphasis added).

"As a gatekeeper, courts are supposed to ensure that the testimony given to the jury is reliable and will be **more informative than confusing**." *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 858 F.3d 787, 800 (3d Cir. 2017) (emphasis added). Additionally, "[b]oth an expert's methodology and the application of that methodology must be reviewed for reliability." *Id.* at 791. The "specific way an expert conducts such an analysis must be reliable; '**all of the relevant evidence must be gathered**, and **the assessment or weighing of that evidence *must not be arbitrary***, but must itself be **based on methods of science.**'"

*Id.* at 796. Here, the application of the proposed methodology is fatally flawed because no method was applied at all. Dr. Thompson's methodology is his conclusory "say so."

The party offering the proposed expert testimony bears the burden of establishing the admissibility of the testimony by a preponderance of the evidence. *Padillas v. Stork-Gamco, Inc.,* 186 F.3d 412, 417-18 (3d Cir. 1999). An "expert's opinions must be based on the methods and procedures of science, **rather than on subjective belief or unsupported speculation**." *Paoli*, 35 F.3d at 742 (emphasis added) (citations and internal quotations omitted). Thus, "the expert must have 'good grounds' for his or her belief." *Id.* (quoting *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 590 (1993)). These good grounds must support each step of the analysis and, "*any* step that renders the analysis unreliable under the *Daubert* factors renders the expert's testimony inadmissible." *Id.* at 745. Here, Dr. Thompson's purported approach is his own, with no reference to the context in this case, without consideration of key facts, documents, and testimony, and he failed to consider any of the requirements applicable to ZHP's manufacturing of generic drugs in order to apply a relevant and reliable standard that fits the case.

Furthermore, "*Daubert*'s gatekeeping requirement .... make[s] certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom **the same level of intellectual rigor that characterizes**

**the practice of an expert in the relevant field**.'" *Elcock v. Kmart Corp.*, 233 F.3d 734, 746 (3d Cir. 2000) (emphasis added) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999)); *see also Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 594 (D.N.J. 2002*), aff'd,* 68 Fed. Appx. 356 (3d Cir. 2003). In addition, the following factors are relevant when determining reliability:

> (i) whether the expert's proposed testimony grows naturally and directly out of research the expert has conducted independent of the litigation (*see Daubert v. Merrell Dow Pharmaceuticals, Inc.,* 43 F.3d 1311, 1317 (9th Cir. 1995)); (ii) whether the expert has unjustifiably extrapolated from an accepted premise to an unfounded conclusion (*see General Elec. Co. v. Joiner,* 522 U.S. 136, 146, 118 S.Ct. 512, 139 L.Ed.2d 508 (1997)); (iii) whether the expert has adequately accounted for alternative explanations (*see Claar v. Burlington, N.R.R.,* 29 F.3d 499 (9th Cir. 1994)).

*Magistrini*, 180 F. Supp. 2d at 594–95. To this end, the Third Circuit has affirmed the exclusion of expert testimony that "failed to consistently apply the scientific methods … articulate[d], … deviated from or downplayed certain well-established principles of [the] field, and … inconsistently applied methods and standards to the data so as **to support [an] a priori opinion**." *Zoloft*, 858 F.3d at 792 (emphasis added). The same outcome is required on this record.

# I.
# DR. THOMPSON'S OPINIONS SHOULD BE PRECLUDED PURSUANT TO *DAUBERT*

## A. Dr. Thompson's Narrow Qualifications and Inadequate Methodology.

Dr. Thompson defined his expertise as "organic synthesis." (Thompson Dep. Tr. 29:20-30:2). **He did no "independent study or analysis of what subjects were in the literature at particular times," even though that is the core of the opinion he is purporting to offer**. (*Id.* at 34:6-11). In fact, **he testified that whether or not "ZHP failed to adequately assess the potential formation of mutagenic impurities when they implemented the new process," as found by the FDA, is "beyond the scope" of his opinion – because he doesn't know what ZHP did**. (*Id.* at 74:17-75:3, 76:23-77:1). Thus, he admitted that the question he purported to answer is beyond the scope, because he actually did not evaluate the question.

Dr. Thompson is not a regulatory expert, as confirmed by defense counsel: "He's not a regulatory expert and said he can't comment on the FDA." (*Id.* at 74:2-4). He also testified that he is not an expert on or offering opinions related to cGMPs. (*Id.* at 33:5-8). Dr. Thompson also admitted he is not an expert in risk assessments and has never done any research into nitrosamines. (*See, e.g.*, *Id.* at 20:12-18, 33:9-12, 62:15-17, 180:13-18, 181:19-25). In fact, he had never considered or been aware of nitrosamines at all before he was retained in this case. (*Id.* at 20:12-21:6, 22:4-

15, 24:4-25:1).[2] These limiting foundational points should factor into the Court's determination of reliability:

> One very significant fact to be considered is whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying. That an expert testifies for money does not necessarily cast doubt on the reliability of his testimony, as few experts appear in court merely as an eleemosynary gesture. But in determining whether proposed expert testimony amounts to good science, we may not ignore the fact that a scientist's normal workplace is the lab or the field, not the courtroom or the lawyer's office.

*Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995); s*ee also Elcock*, 233 F.3d at 747 (quoting *Paoli*, 35 F.3d at 742, n.8).

**Dr. Thompson did not apply any standard for analyzing the potential risks of a generic API manufacturing process, including the risks of creating genotoxic impurities**. He point blank admitted he didn't take into account any standards or internal protocols and did not know what ZHP was required to do. (Thompson Dep. Tr. 61:8-62-3, 65:5-22, 85:8-24). This matters since his report is focused on what the people at ZHP should have known. Instead of applying an

[2] Dr. Thompson also confirmed that he did address the application of gas chromatography or mass spectrometry to the peaks seen on the chromatograms in his report, and what ZHP should have been looking for in evaluating unknown peaks because that was not addressed in his report and is "outside the scope of [his] opinion." (*Id.* at 97:22-99:8, 103:2-104:8).

objective standard, he simply framed his analysis in terms of what he says he did or knew in his small-scale research lab, which is subjective, unreliable, and irrelevant. *See Paoli*, 35 F.3d at 742-743 (holding an "expert's opinions must be based on the methods and procedures of science, **rather than on subjective belief or unsupported speculation**," and "admissibility depends in part on 'the proffered connection between the scientific research or test result to be presented and particular disputed factual issues in the case.'"); *In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig. (No. II)*, 341 F. Supp. 3d 213, 241 (S.D.N.Y. 2018) (holding, **"[M]ethodology ... aimed at achieving one result ... is unreliable, and ... must be excluded"** (quoting *Faulkner v. Arista Records LLC*, 46 F. Supp. 3d 365, 381 (S.D.N.Y. 2014)).

Though proffered as an expert in organic synthesis, **Dr. Thompson admitted that he could not opine on the fundamental question he was ostensibly brought to address, which was "whether ZHP was responsible to identify the potential risk of forming these genotoxic impurities even if it was not, to quote you, obvious and easy to catch**." (Thompson Dep. Tr. 67:20-24 (emphasis added)). If he can't opine on that issue, there is no point to his testimony, especially given his concessions that scientific research done at the time would have shown (1) dimethylformamide contains and degrades into dimethylamine, (2) dimethylamine and sodium nitrite create NDMA, as occurred in ZHP's valsartan manufacturing

process here, and (3) the technology to test for and detect NDMA was available. (*Id.* at 91:10-19, 96:6-97:5, 104:9-105:1).

And to top it off, Dr. Thompson was unable to answer when asked what ZHP needed to do if it knew this information, claiming it was "outside the scope." (*Id.* at 93:23-20).

Dr. Thompson admitted that **he did not know "what standards applied to the people at ZHP who were the process chemists in terms of what the standard was for them in terms of what they were supposed to do in order to evaluate potential formation of genotoxic impurities**." (*Id.* at 61:8-17; *see also id.* at 61:19-62:3, 65:16-22, 85:8-24 (emphasis added)). **Dr. Thompson actually admitted he was not an expert in this area**. (*Id.* at 33:9-12). Thus, by his own admission, he is not an expert about, and did not even know what standards applied to, the actual question he purported to answer.

Dr. Thompson was completely unaware, based on the FDA guidance adopted per ZHP's own regulatory filings, that **ZHP was "required to make every feasible technical effort to prevent the formation of genotoxic or carcinogenic compounds during the manufacture of valsartan**." (FDA, Guidance for Industry, *Genotoxic ad Carcinogenic Impurities in Drug Substances and Products: Recommended Approaches*, p. 7 (Dec. 2008) (Ex. 4); HUAHIA-US00007898 (stating, "FDA draft guideline "Genotoxic and Carcinogenic Impurities in Drug

Substances and Products: Recommended Approaches' is applicable to the applications for existing active substances") (Ex. 5)). He did not even pay lip service to whether or not ZHP performed any analysis, because he does not know what ZHP did. Unaware of the required scope of the scientific evaluation, he was never in a position to measure ZHP's conduct (which he did not evaluate) against that or any other relevant or reliable standard—and thus only applied his own personal standard of "things you can think of." (*Id.* at 61:2).

Dr. Thompson also did not even know of or apply ZHP's internal SOPs, such as its Guideline for Genotoxic Impurity Evaluation, which required "[a]ll intermediates and APIs produced under GMP conditions [to] be identified for genotoxic impurities."[3] And since he didn't know this was a required "should have known" and a fundamental point of the risk assessment, he did not measure the evidence to determine whether or not this could or should have been accomplished based on the scientific literature he admits was available to notify a researcher of the potential formation of NDMA in ZHP's valsartan. His personal opinion is thus untethered and cannot fit the case, and would be hopelessly confusing to a jury.

To the extent Dr. Thompson may be qualified to discuss the organic chemistry literature in general, that is not a helpful fit to the case since he is incapable of offering an opinion tying the contents of the literature to the assessment ZHP's

[3] (Peng Dong 3/29/2021 Dep. Tr. 33:13-19 (Ex. 6); *see also id.* at 33:9-62:16).

chemists were required to perform, and he admits the literature was available anyway. The only standard he applied was what he knew at the time, and he repeatedly reverted to what he knew or did in his small-scale research lab—even when he couched his opinion in terms of "industry practice":

> Q. And when you talked about industry practice, you were basing that on your own experience and the work that you did in your own labs; correct?
>
> * * *
>
> THE WITNESS: Yes.
>
> Q. You didn't do a study or analysis of what other people were doing or what was being done across the industry, you based it on your own experience in your own work; correct?
>
> A. Yes.

(Thompson Dep. Tr. 86:25-87:11). When shown the FDA's Warning Letter, he admitted that he did not read it, and deemed it "irrelevant to the issue that I was providing an opinion on, yes." (*Id.* at 68:13-69:22). This despite the fact that the FDA told ZHP that it "disagreed that pointing to current industry practice is adequate as a defense due to the failure to do [the required] type of [risk] analysis." Dr. Thompson's response was: "It's outside the scope." (*Id.* at 87:12-18). A methodology that relies only on favorable FDA statements, and disregards unfavorable FDA statements has to be hopelessly flawed. (S*ee, e.g.*, Thompson R.

5). And Dr. Thompson conceded that he "cherry-picked" the documents that he wanted to rely on by his own admission. (Thompson Dep. Tr. 56:16-24).

His decision to disregard FDA findings critical of ZHP is all the more methodologically unsound in light of his heavy reliance on FDA statements and actions throughout his report when he felt they could be used to support ZHP's defense. (*Id.* at 87:12-15; *see, e.g.*, Thompson R. 5). But even that purported reliance was methodologically unsound since he wasn't even able to tell what FDA statements he was actually relying on. (Thompson Dep. Tr. 67:25-68:12). His approach was conclusion driven, not driven by determining the objectively correct answer.

His cherry-picking approach to the FDA is very telling since the central source of information Dr. Thompson relies on, in addition to his own narrow experience, is his interpretation of FDA statements. But he is not a regulatory expert and does not work with or rely on FDA statements, and did nothing to independently verify or refute, or understand the full context of what the FDA said. He admitted a big hole in his methodology, as he had no idea that the FDA rejected ZHP's argument that the chemical reactions at issue could not be known. When shown the FDA's conclusion that ZHP should have known, he simply stated that he disagreed with the FDA, without any sound reasoning to do so. (*Id.* at 69:12-18, 70:5-7, 70:23-71:16, 72:21-73:23, 74:17-76:2, 79:18-80:9, 80:23-81:6, 80:17-82:2, 85:25-88:1). As

shown above, he did this based on no research and no objective basis, it is simply the conclusion he preferred to reach. *Daubert* prohibits this type of subjective, conclusion-driven cherry picking and/or gamesmanship, claiming reliance when it suits the expert and ignorance when it does not. *Mirena*, 341 F. Supp. 3d at 241 (S.D.N.Y. 2018) (holding, **"[M]ethodology ... aimed at achieving one result ... is unreliable, and ... must be excluded"** (quoting *Faulkner*, 46 F. Supp. 3d at 381)).

Dr. Thompson applied this unreliable approach to attempt to deflect evidence undercutting his conclusory opinions. As already noted, Dr. Thompson conceded that scientific research at the time would have shown (1) dimethylformamide contains and degrades into dimethylamine and (2) dimethylamine and sodium nitrite create NDMA, as occurred in ZHP's valsartan manufacturing process here. (*Id.* at 96:6-97:5). In order to undercut these two critical facts, Dr. Thompson simply said: "**[I]t never enters into my mind when I suggest DMF as a solvent. I never think of it.**" (*Id.* at 77:15-16 (emphasis added)). He later explained, "**I mean, it's one of those factoids, it just doesn't -- doesn't stay unless it's continuously reinforced**." (*Id.* at 92:24-93:2 (emphasis added)). His untethered knee jerk rejection of the scientific literature as a legitimate and required source of information to be consulted by ZHP, despite the regulatory guidances requiring this, is methodologically unsound. That he does so based on elevation of his own practice in a small-scale

research lab without reference to what ZHP—a commercial manufacturer—was required to do is fatal.

In granting a motion to preclude an expert under *Daubert*, this Court has observed:

> [C]ourts also need not admit mere conclusions or opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered…. Mere assumptions, without causal evidence or methodological analysis may be inadmissible.... Conclusions based only on the expert's experience, and testimony founded on methods that are not generally accepted or lack testable hypotheses may also fail to surmount the *Daubert* standard.

*Player v. Motiva Enterprises LLC*, No. Civ. 02–3216(RBK), 2006 WL 166452, at *6-7 (D.N.J. Jan. 20, 2006) (citations omitted). In *Player*, this Court found the expert failed to satisfy the reliability requirement, as the expert failed to consider important facts without satisfactory explanation, among other things. *Id.* at *7. The Court held: "**His method is untestable and arbitrary, without a generally accepted, established, or peer reviewed methodology, and his evaluation was conducted without any real standards**." *Id.* at *8, emphasis added. By failing to apply any of the internal or external standards applicable to what ZHP was required to do in order to evaluate the risks of ZHP's process changes—the "should have known"

question he purports to opine on—Dr. Thompson followed no reliable scientific methodology.

**B. Dr. Thompson Impermissibly Relied on His Own, Baseless Interpretation of the July 27, 2017 Email to Claim the Email Does Not Say ZHP's Valsartan Was Contaminated with NDMA Due to the Sodium Nitrite Quenching Process.**

Dr. Thompson also applied his own unreliable personal interpretation methodology to his speculative interpretation of the July 27, 2017 email. He did this so he could disregard what ZHP's 30(b)(6) witness and ZHP itself, in a translation submitted to the Court, have already agreed it said. (Ex. 7). In fact, Dr. Thompson admitted "**I don't have much of a basis for saying that**" Plaintiffs' and ZHP's, understanding of the email is wrong. (Thompson Dep. Tr. 106:13-14). Such baseless ipse dixit is not helpful to a jury and is impermissible under *Daubert*. *See, e.g.*, *Player*, 2006 WL 166452, at *6-7.

As the Court is aware, the email was sent by ZHP drug impurity researcher Jinsheng Lin, Ph.D. to numerous high-level ZHP employees and matter-of-factly and CORRECTLY stated in part that ZHP's valsartan contained NDMA, and that it formed due to the sodium nitrite quenching—the root cause that has been admitted by ZHP. As testified to by Dr. Lin's boss, Min Li during his 30(b)(6) deposition, the email stated in part:

> Through the secondary mass spectrometry analysis, it can be inferred that the extra NO substituent is in the cyclic compound fragment, and it is very likely that it is an N-

> NO compound; **it is similar to the N-nitrosodimethylamine that occurs in valsartan when quenched with sodium nitrite, and its structure is very toxic.**

(Min Li 4/20/2021 Dep. 87:19-88:7, 88:13-89:18 (Ex. 8) (quoting Ex. 9) (emphases added)). Instead of relying on or even acknowledging Min Li's reading of the email, which is binding on ZHP, Dr. Thomspon read and interpreted the translated email himself to essentially delete the most important phrase:

> A. **So . . . . my first impression when I read this was it was not -- the English -- whoever did the interpretation got it wrong. I didn't believe those words. I see them there, but I don't -- I didn't believe them**.

(*Id.* at121:15-21). Dr. Thompson is a proposed expert witness, he cannot say this to a jury. He is completely unqualified and has no reliable basis for this opinion. Dr. Thompson cannot transform himself into a fact witness by re-interpreting the document without "much of a basis" in a way that directly contradicts ZHP's own translation of the document. (Thompson Dep. Tr. 106:13-14).

### C. Dr. Thompson's Testimony Interpreting and Applying the Chinese Certificate of Analysis Standard Should Be Precluded.

Dr. Thompson also purported to interpret and apply the Chinese standard applicable to the contents of a certificate of analysis (these documents were provided to him after his report was written, and he provided no supplemental report addressing them). Notwithstanding, when asked about his basis to do so, he admitted

that didn't understand what actually happened in the manufacturing process, or what substances were present, and he was "speculating."

> Q. And let's go now back to the calculation on page 6. You mentioned that the alkalinity could be due to bases including dimethylamine and a few other substances. Can you tell me again what those substances are?
>
> A. So hold on. Let me get to the equation. The possibility -- so one of the possibilities potentially -- I mean, the bases that would be stable in DMF would be a carbonate base. Now I see methoxide for methylformate. There could be methoxide in there. There's a number of different bases that could be in there. Not just -- there's a number of different bases that could be in there.
>
> Q. Well, I want to know the ones that you can identify for me. You said carbonate base or methoxide?
>
> A. Carbonate base -- yeah, so methylformate and methylamine, that will give off methanol, not methoxide. So -- **and I don't know if they used carbonate in the process at all, if there are any catalysts that use it. So this -- you know, I don't know exactly if they just mix those two ingredients with no catalyst and heat them up, or what they do,** but...
>
> **So I'm just -- you know, assuming there's a catalyst, there could be things that come off the catalyst that are bases, like carbonate**. You know, that's -- so that's a total base content. Otherwise they would just say this is the amount of dimethylamine in there. Why don't they say that? Why do they say calculated as dimethylamine? **There must be other bases in there for them to make a generic formula like that.**
>
> **Q. You're speculating as to that; correct?**
>
> **A. I'm speculating.**

* * *

**THE WITNESS: Yeah, of course I'm speculating. I'm sorry. Yes, I'm -- I didn't put the formula together. I'm speculating.**

BY MR. SLATER:

Q. The only base referenced here is dimethylamine; correct?

A. Yes.

(Thompson Dep. Tr. 165:15-167:7 (emphasis added)).

The admission that the analysis of the standard is based on speculation and a lack of knowledge about what actually happened and was present in the process at issue should result in the preclusion of any opinions regarding the Chinese standard and the certificates of analysis.

## CONCLUSION

For the foregoing reasons, Dr. Thompson failed to adopt or apply a reliable methodology, and he should therefore be precluded from offering any of his proffered opinions.

Respectfully,

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